

REMARKS

Entry of this Amendment and reconsideration of the present application as amended are respectfully requested.

Claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 83-95 are pending in this application. Claims 2-4, 9, 80 and 82-84 are withdrawn from consideration and claims 18-39, 43, 45-65, 69-77 and 79 have been canceled. Since the Examiner addressed claims 2-4 in the Office Action at page 4, last paragraph, clarification as to whether these claims are still withdrawn from consideration is respectfully requested.

Claims 5, 89, 91 and 92 are amended. Unless an argument is made below directed to the novelty of each change to the claim in view of cited prior art, the changes to the claims do not relate to patentability.

Claim Rejections

Claims 1-8, 13-17, 40, 42, 44, 66-68, 78, 81 and 85-95 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Peters et al. (U.S. Pat. No. 5,442,445). Claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Peters et al. in view of Kaplan et al. (U.S. Pat. No. 3,908,660). It is pointed out that claims 10, 41, 83 and 84 were not rejected in view of prior art, although claims 83 and 84 appear to be addressed in paragraph 7. Clarification of the status of these claims in the next communication is respectfully requested.

In the Office Action, the Examiner states that Peters teaches a tube for attaching to a bowel, comprising a tubular body 11 having a front end adapted to be inserted into a bowel and straps 25 for securing the device to the bowel. Also, the Examiner states that Peters et al. discloses the claimed device except for a sewing ring, but that "it would have been an obvious matter of design choice to use straps instead of a sewing ring since both perform the substantially identical function of securing the device to the bowel and Applicant has not disclosed the sewing ring solves any stated problem and it appears that device would perform equally well with the straps disclosed in Peters,

since Peters states... that other securing elements such as ligatures could be used instead of the straps” (see col. 4, lines 1-7). Further, the Examiner states that “ligatures are sutures that are sewn during surgery, thus the prior art teaches that both strapping and sewing work equally well to prevent the tube from slipping out of the bowel.”

The Examiner’s positions are respectfully traversed on the grounds that:

1. It is not relevant to an obviousness determination whether it would have been obvious to use a prior art structure (straps) instead of the claimed invention (a sewing ring).
2. There are significant problems solved by the sewing ring on the bowel attachment tube in accordance with the claimed invention which result in the claimed invention performing substantially better than the straps of Peter et al.
3. Reliance on the disclosure of the use of ligatures instead of straps in the Peters et al. irrigation tube is misplaced since the ligatures contemplated by Peters et al. are not sewn during surgery.

Each of these arguments will be addressed separately below.

1. The Examiner states that it would have been an obvious matter of design choice to use straps as in Peter et al. instead of a sewing ring. This is not believed to be the proper inquiry for obviousness; rather, the proper inquiry is believed to be whether the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains (35 U.S.C. §103(a)).

Therefore, it is immaterial whether one would use straps instead of a sewing ring. Indeed, the invention is the presence of a sewing ring on a tube for attachment to bowel so the Examiner’s statement would appear to be useful in refuting patentability to one attempting to patent a strap on a bowel attachment tube in view of the claimed invention.

What is not obvious is to use a sewing ring as in the present claimed invention instead of a strap as in Peter et al. for the reasons set forth below.

2. The sewing ring on the bowel attachment tube in accordance with the invention solves significant problems when attaching bowel to the tube so that it would not have been obvious to one skilled in the art to use a sewing ring instead of a strap.

The first problem relates to movement of the bowel before it is attached or otherwise secured to the tube. With the Peters et al. device, the forward end of the drain tube 1 is first inserted into the bowel 41, and then the straps 25 tied around the bowel 41 and tube 1 to secure the tube 1 inside the bowel 41 (see col. 4, lines 8-24). However, before the straps 25 are tied around the bowel 41, the bowel 41 can slip off of the tube 1.

Slippage of the bowel off of a tube is avoided in the present invention by the presence of the sewing ring on the tube having its unique shape, i.e., with the “undercut rear surface defining a circumferentially extending notch ...”. The sewing ring provides a means by which the surgeon can quickly grasp and clamp the open bowel and the tube together before the bowel is attached or otherwise secured to the tube, i.e., before straps are applied as in Peters et al. Grasping and clamping the tube and bowel together about the sewing ring, e.g., with surgical forceps, can be done more rapidly than applying straps to thereby reduce the amount of time that the bowel could potentially slip off of the tube. Then, after the bowel and tube are secured together with the surgical forceps, there is plenty of time to devote to properly secure the bowel to the tube, e.g., using straps or a filament, without inadvertent separation of the bowel from the tube and spillage of bowel content.

Therefore, the present invention provides a novel solution to the problem of a bowel slipping off of a tube after it is positioned around the tube and before it is secured to the tube, e.g., by straps or a filament, by providing a structure (the sewing ring) which enables a very quick procedure to provide an interim and temporary securing of the bowel to the tube. This quick procedure is the clamping of the bowel to the sewing ring by forceps which is enabled by the “undercut rear surface ...” of the sewing ring.

The second problem relates to separation of the bowel from the tube after the straps have been applied. When straps are used to secure bowel to a tube as in Peters et al., it is possible for the

bowel to slip off the tube before, during or after the irrigation, because the inner surface of the bowel is slippery and can cause the tube to slip out of the bowel even when the straps are applied and thought to be secure. If this occurs, contamination of the sterile abdominal cavity can be catastrophic.

Slippage of the bowel off of the tube is prevented by the tube in accordance with the present invention by the construction of the sewing ring with its undercut rear surface to enable a filament to be passed through the bowel and the sewing ring such that the bowel and sewing ring can be sewn together. Sewing the bowel and tube together provides a considerably greater connection between the bowel and the tube, which does not occur when straps are used, and therefore significantly reduces the possibility of the bowel separating from the tube during irrigation.

The foregoing problems are explicitly disclosed in the specification. For example, the specification at page 2, lines 10-13 recites that “[f]or example, problems arise in the prior art drain tubes in that the edge of the bowel is not easily and securely attached to the drain tube. A more secure and convenient attachment system for attaching an edge of the bowel to a drain tube is thus needed.” Objects of the invention are set forth at page 2, lines 22-23, “[a]nother object of the present invention is to provide a drain tube with a convenient and reliable system for securing an edge of the bowel to the drain tube” and at page 2, lines 24-26, “[a]nother object of the present invention is to provide a drain tube and irrigation apparatus which will minimize contamination of the sterile abdominal cavity and abdominal wound by organisms from the bowel.” The specification also discloses how these problems are solved by the tube including the sewing ring, e.g., at page 3, lines 6-14, page 4, lines 23-27, page 8, line 20 to page 9, line 5, page 9, line 18 to page 10, line 15, and page 10, line 29 to page 11, line 7.

3. Reliance on the disclosure of the use of ligatures instead of straps in the Peters et al. irrigation tube is misplaced since the ligatures contemplated by Peters et al. are not sewn during surgery.

The Examiner noted that Peters et al. mentions the possibility of using ligatures instead of

straps 25 to secure the bowel 41 to the tube 1 and takes the position that ligatures are sutures that are sewn during surgery.

Initially, this has little if any bearing on the novelty of the invention because even if one were to use ligatures which are sewn instead of straps, this does not overcome the fact that Peters et al. does not disclose, teach or suggest a sewing ring having the particular shape recited in independent claim 78, and further that it would not have been obvious to provide such a sewing ring instead of the straps as in Peters et al.

Moreover, it is respectfully pointed out that ligatures are not considered sutures but rather ties. A suture has a thread or filament attached to a needle and is passed, for example, into tissue around a vessel and used to tie the tissue and the vessel closed. The ligatures contemplated by Peters et al. are simply threads or filaments which are not attached to a needle to be passed through the structure of the tube 1 but rather are simply wound around the tube instead of the straps 25 and do not pass through the bowel and any part of the tube.

In conclusion, independent claim 78 includes a novel feature of the sewing ring having a particular construction to enable several problems with prior art bowel attachment tubes to be solved. The particular construction of the sewing ring is not disclosed in the cited prior art nor an obvious matter of design choice based on the cited prior art. Therefore, claim 78 and dependent claims 1, 5-8, 11-17, 40, 42, 44, 66-68, 81 and 85-95 are patentable over Peters et al., taken individually and in combination with Kaplan et al.

Moreover, Peters et al. does not disclose features of the dependent claims. For example, Peters et al. does not disclose, teach or suggest a bowel sheath as now set forth in claims 5, 91 and 92. The bowel sheath 3 of Peters et al. is arranged around the side arm 12 to "provide an extended handle allowing the drain tube to be gripped without having to touch the tube 3" (col. 3, lines 18-22). Sheath 3 does not have a first position in which the sewing ring is exposed to enable the bowel to be attached to the sewing ring and a second position in which the bowel sheath is extended over the front end of the tubular body (that end adapted to be inserted into the bowel) and overlies the sewing

ring. This is not a situation of a rearranging of parts which involves only routine skill in the art because the side arm and front end of the tubular body serve fundamentally different purposes, i.e., to facilitate insertion of the tube into the bowel or to enable the tube to be grasped. The presence of a sheath on the handle for gripping purposes does not equate to a sheath on a front end of the tube for maintaining the sterility of the operative area as in the invention (see page 11, lines 14-15).

In view of the foregoing, it is respectfully submitted that the Examiner's rejections of claims 1, 5-8, 11-17, 40, 42, 44, 66-68, 78, 81 and 85-95 have been overcome and should be removed.

Double Patenting

Claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 were provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 12, 25 and 26 of U.S. patent application Ser. No. 11/189,305. The Examiner is respectfully requested to reconsider this rejection in view of the abandonment of the '305 application.

Request for Interview

Applicant hereby requests a telephonic interview to discuss continued prosecution of this application upon entry of this amendment. It is noted that this is the fourth Office Action for this application, pending since September 26, 2003, and the applicant would like to discuss the merits of this application to possibly expedite an allowance of subject matter disclosed therein.

Should any changes to the claims and/or specification be deemed necessary to place the application in condition for allowance, the Examiner is respectfully requested to contact the undersigned to discuss the same.

It is believed that this Amendment is being timely filed. In the event that any other extensions and/or fees are required for the entry of this Amendment, the U.S. Patent and Trademark Office is specifically authorized to charge such fee to Deposit Account No. 50-1268 in the name of Brian Roffe.

Application Ser. No. 10/672,053
Response to Office Action dated May 13, 2008
Amendment dated August 13, 2008

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

/Brian Roffe/

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